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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,403	08/30/2001	David Botstein	P2548P1C6	2331

7590

03/01/2004

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,403	BOTSTEIN ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 25-28 and 32-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 25-28 and 32-37 are pending in the instant application. Claims 25-28 and 33 have been amended, claims 22-24 and 29-31 have been canceled and claims 35-37 have been added as requested by Applicant in the Paper filed Dec. 15, 2003.

Newly submitted claim 37 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the polypeptide of claims 25-28 and 32-36 and the method of claim 37 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in the claimed method of inhibiting neoplastic growth of tumor cells, but the polypeptide can be used in another and materially different process such as in a method of generating antibodies.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 37 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Oath/Declaration

2. The objection to the oath is withdrawn due to the removal of the inventor from the application pursuant to a 37 CFR § 1.48(b) letter filed Dec. 15, 2003.

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Objection to Specification

3. The objections to the specification, including title and abstract, are withdrawn in view of Applicants' amendment.

Withdrawn Objections and Rejections

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Double Patenting

5. Applicant's statement on page 9 of the response that to the best of its knowledge, no claims of the present application conflict with claims presented in applications containing SEQ ID NO: 362, is acknowledged and accepted as a complete reply to the requirement under 37 CFR 1.105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 25-28 and 32-34 remain rejected and new claims 35 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard et al., US Patent No. 6,197,930, issue date March

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6, 2001, effective priority date August 26, 1997, for reasons of record in the previous Office Action, at page 5, and below.

New claims 35 and 36 are drawn to a polypeptide that comprises conservative amino acid substitutions or 0-12 amino acid additions, deletions or substitutions of SEQ ID NO: 42, wherein the polypeptide inhibits neoplastic growth in tumor cells. Shepard et al. teach amino acid substitutions, deletions and insertions, and conservative amino acid changes.

Applicants traverse the rejection and assert that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference, and cite *Verdegaal Bros. V. Union Oil Co. of California*, and that as amended, all claims of the present application recite – or depend from claims that recite – a functional limitation not found in the Sheppard patent, namely, the claimed polypeptide inhibits neoplastic growth in tumor cells. Applicants further assert that since the Sheppard reference does not teach that the protein inhibits neoplastic growth in tumor cells, it does not anticipate the claims.

Although Shepard et al. did not disclose that the protein of SEQ ID NO: 2 could inhibit neoplastic growth in tumor cells, the polypeptide of Sheppard et al. would have inherently possessed that activity, or any activity of the protein, since the protein of Sheppard et al. is identical to the protein of the instant application (Ex parte Novitski, 26 USPQ2d 1389). There is no evidence that the prior art product does not inherently possess the characteristics of the claimed polypeptide.

See Ex parte Gray, 10 USPQ 2d 1922: “Applicant can be required to prove that prior art products do not inherently possess characteristics of the claimed proteins.”, and

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In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977): “When claimed product and prior art product reasonably appear to be the same, the burden of proof is on Applicant to demonstrate a novel or unobvious difference between the claimed product and that of the prior art.”. Therefore, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1 Claims 35 and 36 are indefinite because a polypeptide cannot encode a polypeptide.

7.2 Claim 35 is also indefinite because it is drawn to a polypeptide of SEQ ID NO: 42 “with conservative amino acid substitutions”, and the language of the claims does not place an upper limit on the extent of the changes to be made. Therefore, the claims fail to adequately point out that which Applicant sees as the invention.

Conclusion

8. No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner

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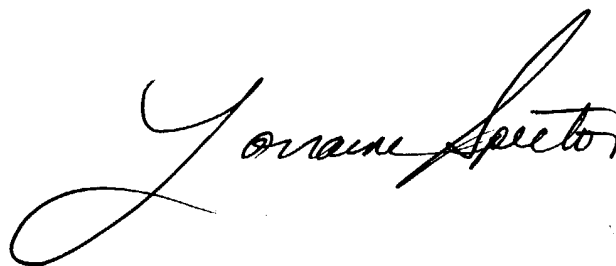
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Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script, reading "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

LORRAINE SPECTOR
PRIMARY EXAMINER